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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,961	03/15/2004	Songshou Mao	13361.4011	2353

34313 7590 12/01/2006

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EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT PAPER NUMBER

3737

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/801,961

Applicant(s)

MAO ET AL.

Examiner

Katherine L. Fernandez

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 26-41 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
-) Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/28/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed June 28, 2004 is acknowledged. The information disclosure statement meets the requirements of 37 C.F.R. 1.97 and 1.98 and therefore the references therein have been considered.

Claim Objections

3. Claim 34 is objected to because of the following informalities: Claim 34 recites the limitation "the optimal scan starting point" in the first line. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 26 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Manning et al. (U.S. Patent No. 6,501,979).

Claim 26 discloses a method for acquiring an image of the heart of a patient by automatically and prospectively triggering an image-acquisition scan during a cardiac cycle, comprising: activating a cardiac imaging apparatus to receive electrical signals to measure the length of an R-R interval of the cardiac cycle; automatically calculating the length of the R-T segment using software that operates the cardiac imaging apparatus; automatically and prospectively triggering the image-acquisition scan at a point determined by the software based on the measurement of the R-R interval and the R-T segment; and displaying the image. Manning et al. teaches a method and apparatus for triggering image acquisition at fixed times with respect to the cardiac cycle, in particular to the R-wave (column 9, lines 43-49). Software is used to implement steps such as detecting cardiac phases (69), generating and outputting synchronization signals (71), and generating and collecting imaging data (73). See Figure 5. This method could also be applied to any other phase of the cardiac cycle (column 9, lines 49-54). The reconstructed image can then be displayed (column 7, lines 8-9).

Manning et al. further teaches that the duration of the various waves and of the intervals between the waves have well-known and tabulated values varying by age, sex, heart rate, disease state, and so forth (column 9, lines 24-26). Manning et al. does not specify that software can automatically calculate the length of the R-T segment. However, since the R-T segment is a cardiac phase, the R-T segment could be automatically calculated when the software detects the cardiac phases, and therefore this limitation is anticipated by Manning et al.. Alternatively, if there is no anticipation, it nevertheless would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the tabulated values to automatically calculate the R-T segment length using software in order to provide real-time processing.

Claims 27, 34-35, and 37-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Manning et al. (U.S. Patent No. 6,501,979).

Referring to claim 27 of the instant application, this claim discloses the step of calculating the R-T segment length to include determining the gender of the patient and the R-R interval length. Manning et al. teaches that the durations of the various waves in the ECG signal can be calculated and have tabulated values varying by age, sex, heart rate, etc. (column 9, lines 24-26).

Referring to claim 34 of the instant application, this claim discloses the method whereby the optimal scan starting point may dynamically vary with each cardiac cycle. Manning et al. teaches that synchronization signals can be generated after each R-wave (column 13, lines 47-50).

Referring to claim 35 of the instant application, this claim discloses a cardiac imaging apparatus comprising: a transmitter that generates an image-acquisition scan; an input console adapted to input data; electrical leads capable of detecting an R-R interval of a cardiac cycle; and software that measures the length of the R-R interval of the cardiac cycle, wherein the software calculates the length of the R-T segment of the cardiac cycle and operates an ECG gating device communicating with the transmitter to prospectively trigger an image-acquisition scan at an optimal scan starting point.

Manning et al. teaches an imaging apparatus that includes a control unit (29), an ECG unit (14), a synchronization unit, and an image-processing unit (26). See Figure 1B. The control unit controls the other units to acquire imaging data and to reconstruct the image (column 7, lines 46-48). The ECG unit is connected to the patient via electrodes (15) and obtains ECG signals (column 8, lines 8-13). Software is used to implement the method, as depicted in Figure 5.

Referring to claim 37, this claim discloses the apparatus comprising a magnetic resonance imaging device. Manning et al. teaches that the invention can be applied to MR imaging (column 2, lines 63-65).

Referring to claim 38, this claim discloses the apparatus comprising a spiral computer tomography scanner. Manning et al. teaches that the invention can be applied to computer tomographic (CT) x-ray imaging (column 2, lines 63-65).

Referring to claim 39, this claim discloses the apparatus comprising an electron beam tomography scanner. Manning et al. teaches that the invention can be applied to computer tomographic (CT) x-ray imaging (column 2, lines 63-65).

Referring to claim 40, this claim discloses the apparatus wherein the software calculates the optimal scan starting point with each cardiac cycle. Manning et al. teaches a method implemented by software of providing synchronization signals based on detected cardiac phases that trigger the collection of imaging data (column 13, lines 45-55).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 28 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. in view of Richey et al. (U.S. Patent No. 4,547,892).

Regarding claim 28, Manning discloses using software to implement the method discussed above. However, Manning et al. does not expressly disclose that the step of triggering the image-acquisition scan is achieved by the software based on a speed of the image-acquisition scan. Richey et al. discloses a method for producing an image of the heart using the patient's ECG signal in a traverse-and-rotate-type CT scanner as a time base for triggering the beginning of a traverse (column 2, lines 8-12). A delay time before issuing a trigger pulse is dependent on, among other factors, the speed of the traverse of the beam (column 3, lines 38-44). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to consider the speed of the image-acquisition scan when determining when to trigger the image-acquisition scan. The motivation for doing so would have been to avoid blurring of the moving heart structures (as taught by Richey et al. in column 3, lines 35-37).

Regarding claim 36, Manning et al. does not expressly teach that the software can be adapted to measure the speed of the image acquisition scan. Richey et al. discloses that the speed of traverse of the beam can be monitored during a scan (column 3, lines 44-45). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified Manning's method such that the software measured the speed of the image acquisition scan, as it is monitored

in Richey's method. One of ordinary skill in the art would have been motivated to do so in order to compensate for variations in the scan speed (as taught by Richey et al. in column 3, lines 44-47).

Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. in view of Heuscher et al. (U.S. Patent No. 6,154,516). As discussed above, Manning et al. discloses the method claimed. However, Manning et al. does not disclose the speed settings of the image-acquisition scan. Heuscher et al. teaches a method for cardiac gated spiral CT imaging where the scan time is selected based on certain parameters as described in column 6, lines 45-64. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have selected a range of scan times for the method described by Manning et al. as taught by Huscher et al. One of ordinary skill in the art would have been motivated to do so in order to reduce the effect of motion on the quality of the image (as taught by Huscher et al. in column 3, lines 43-44).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 26-39, and 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8, 10, and 13-17. of U.S. Patent No. 6,708,052 in view of Manning et al. (US Patent No. 6,501,979).

Claim 26 of the instant application discloses a method of acquiring an image of the heart of a patient by prospectively triggering an image-acquisition scan during a cardiac cycle comprising: measuring the length of an R-R interval of the cardiac cycle; calculating the length of the R-T segment; and prospectively triggering the image-acquisition scan at a point based on the measurement of the R-R interval and the R-T segment, as specified in claim 1 and in claim 6 of the patent. However, claim 26 of the instant application does not teach that the functions stated above would be automatically carried out by software that operates the cardiac imaging apparatus and that an image would be displayed. In the same field of endeavor, Manning et al. teaches using software to implement a method for combined ECG and PPU controlled magnetic resonance imaging (column 12, lines 40-45). As noted in the flow chart of figure 5, the software is designed to carry out functions such as determining cardiac phases (69), generating and outputting synchronization signals (71), and generating

and collecting imaging data (73). The reconstructed image can then be displayed (column 7, lines 8-9). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used software to implement the method described above of the instant application, as taught by Manning et al., to provide the advantages of real-time processing and ease of use.

Referring to claim 27, this claim has the same limitation as claim 10 of the patent.

Referring to claim 28, this claim discloses the method wherein the step of triggering the image acquisition scan is based on a speed of the image-acquisition scan, as specified in claim 6 of the patent where the step of triggering the image acquisition scan is referred to as the optimal scan starting point. However, claim 28 of the instant application does not teach that the software achieves this step. It would have been obvious to one of ordinary skill in the art at the time of the invention to have used software to implement this function, as taught by Manning et al., to provide the advantage of real-time processing.

Referring to claim 29, this claim discloses applying the algorithm $RT \pm X$ where said X value depends on the R-R interval length and a speed of said image-acquisition scan, as specified in claim 7 of the patent. However, claim 29 of the instant application does not teach that software would be used to apply the algorithm. It would have been obvious to one of ordinary skill in the art at the time of the invention to have used software to apply the algorithm, as taught by Manning et al., to provide the advantages of real-time processing.

Referring to claim 30, this claim has the same limitation as claim 2 of the patent.

Referring to claim 31, this claim has the same limitation as claim 3 of the patent.

Referring to claim 32, this claim has the same limitation as claim 4 of the patent.

Referring to claim 33, this claim has the same limitation as claim 5 of the patent.

Referring to claim 34, this claim has the same limitation as claim 8 of the patent.

Referring to claim 35, this claim discloses a cardiac imaging apparatus comprising: a transmitter that generates an image-acquisition scan, an input console adapted to input data, and an ECG gating device communicating with the transmitter to prospectively trigger an image-acquisition scan at an optimal scan starting point, as specified by claim 13 of the patent. However, claim 35 of the instant application does not teach electrical leads capable of detecting an R-R interval of cardiac cycle, and software that measures the length of the R-R interval of the cardiac cycle, wherein the software calculates the length of the R-T segment of the cardiac cycle, and operates the ECG gating device. Manning et al. teaches the use of a medical imaging apparatus which comprises of an ECG unit which is connected to the patient via electrodes (column 8, lines 8-13) and is capable of detecting R-waves. As described above, Manning et al. also teaches the use of software to implement the functions stated above. See Figure 5. It would have been obvious to one of ordinary skill in the art at the time of the invention to have used electrical leads to detect the R-R interval of the cardiac cycle and to use software to carry out the functions, as taught by Manning et al., to provide the advantages of real-time processing and ease of use.

Referring to claim 36, this claim discloses measuring the speed of the image acquisition scan, as specified in claim 13 of the patent. However, claim 36 of the instant

application does not teach that the software is adapted to perform this function. It would have been obvious to one of ordinary skill in the art at the time of the invention to use software to perform this function, as taught by Manning et al., to provide the advantages of real-time processing and ease of use.

Referring to claim 37, this claim has the same limitation as claim 14 of the patent.

Referring to claim 38, this claim has the same limitation as claim 15 of the patent.

Referring to claim 39, this claim has the same limitation as claim 16 of the patent.

Referring to claim 41, this claim discloses storing the gender of a patient, as specified in claim 17 of the patent. However, claim 41 of the instant application discloses that the software receives data from the input console and stores the gender of a patient whereas claim 17 discloses that the ECG gating device receives and stores the gender of said patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to have the software perform this function, as taught by Manning et al., to provide the advantages of real-time processing and ease of use.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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